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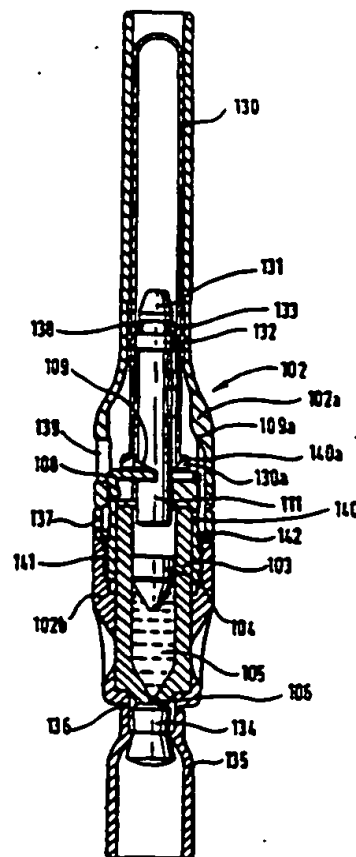
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<p>(21) International Application Number: PCT/GB96/00551</p> <p>(22) International Filing Date: 8 March 1996 (08.03.96)</p> <p>(30) Priority Data: 9504878.1 10 March 1995 (10.03.95) GB</p> <p>(71) Applicant (for all designated States except US): WESTON MEDICAL LIMITED (GB/GB); 2a Hales Barn Workshops, New Street, Stradbroke, Eye, Suffolk IP21 5JG (GB).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): WESTON, Terence, Edward (GB/GB); Thornlea, Pixey Green, Stradbroke, Eye, Suffolk IP21 5NG (GB).</p> <p>(74) Agent: ELKINGTON AND FIFE; Prospect House, 8 Pembroke Road, Sevenoaks, Kent TN13 1XR (GB).</p>	<p>(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>	

(54) Title: **SPRING-POWERED DISPENSING DEVICE**

(57) Abstract

A device is described for dispensing a material or article, comprising a dispensing member which moves under the force of a spring providing an energy store. A damping arrangement employing a viscous damping medium such as grease is used to damp recoil during dispensing. In particular, such a damping arrangement is shown applied to a needleless injector operating by impact on dispensing piston.



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SPRING-POWERED DISPENSING DEVICE

This invention relates to a dispensing device which employs a spring (which may, for example, be of metal or compressed gas) to urge a dispensing member to dispense, for example, a dose of liquid, powder, or a pellet.

Spring powered dispensers are in common use. For example in the medical field, there are automatically operated injectors for delivering medicaments to the tissues. Generally the device is placed on the patient's skin, and a release button is operated which unlatches a pre-loaded spring that drives the hypodermic needle through the epidermis, and thereafter pumps the medicament into the tissues. At the instant of release, the housing of the injector reacts against the mass of the driven piston in the reverse direction of the injection - that is, it recoils. This is wasted energy, although in the case of simple injectors, the recoil is resisted by the user's hand, and a larger proportion of the spring force is directed to moving the needle and medicament.

More sophisticated devices aim to apply a predetermined force to the skin, so that the optimum placement conditions are met before the device may be operated. Examples of the latter may be found in the needleless injectors disclosed in PCT/GB94/01608 (WO95/03844) by the present inventor. In these examples it is convenient to apply the force via a sleeve or ring acting through a spring, so that the user grasps the sleeve or ring, and presses the delivery orifice of the injector onto the skin. When the displacement of the sleeve reaches a predetermined value corresponding to the desired contact force on the skin, it operates a release mechanism which causes the injection. At the instant of release, the injector body, which is effectively "floating" within the operating sleeve, recoils away from the injection site, reacting against the operating sleeve spring. This represents wasted energy, since ideally, all of the spring

energy should be directed to driving the medicament into the tissues, not in moving the injector body in the opposite direction.

It is possible to use a substantial spring to urge the injector via the operating sleeve onto the patient's skin, and thereby reduce the recoil by coupling the injector body through the spring and sleeve to the mass of the user's hand. However, this results in an unacceptable high pressure on the skin and/or trigger mechanism. For example, a needleless injector must be pressed onto the skin with a relatively light force for a subcutaneous injection, otherwise the subcutaneous tissues are compressed too much, resulting in a faulty injection.

Other devices which may employ pre-loaded spring energy to deliver a metered dose of liquid or powder, include breath-actuated metered dose inhalers (MDI's), automatic bactericide dispensers, and guns. In all cases where the user does not hold the device member on which the power spring reacts there is the potential of energy wastage. Many of these devices are intended for single use, or must be discrete - that is, small and lightweight, and it is important that the stored energy is used efficiently.

According to the present invention there is provided a device for dispensing a material or article comprising a dispensing member movable, to effect dispensing, under the force of a spring which provides an energy store, and damping means, having a viscous damping medium, for damping recoil of the device during dispensing.

In a preferred embodiment, the invention is applied to a needleless injector. We have obtained significant improvements in operating characteristics of a needleless injector by applying the skin contact force to the injector body via an operating sleeve coupled to the injector body by a highly viscous grease. The grease is sufficiently soft to permit relatively slow sleeve displacement to operate the release mechanism, but at the instant of

release the high viscosity grease prevents the rapid recoil of the injector body relative to the operating sleeve. Of course, the injector is coupled momentarily to the operating sleeve, so that the combination attempts to recoil, but since at the instant of release the user's hand is firmly gripping the sleeve, most of the recoil is prevented, and a higher proportion of the power spring energy is employed in dispensing the injectate.

A further benefit arising from the invention that the risk of inadvertent operation is greatly reduced, since trigger operating resulting from a sharply applied force (caused by dropping the injector, clumsy handling, or too rapid application) is resisted by the damping grease.

In a preferred embodiment, a needleless injector having a cylindrical body is operated by pressing the discharge nozzle onto the patient's skin by acting on a close-fitting concentric sleeve, which, when displaced relative to the injector body releases the spring powered ram to cause the injection. A longitudinal groove in the wall of the injector body contains the high viscosity grease, and a cooperating key on the operating sleeve is a close sliding fit in the groove. Gentle pressure on the sleeve causes it to move on the injector body in a smooth, damped motion; rapid movement is strongly resisted by the high viscosity grease which inhibits the key from paid movement in the groove. When the injector "fires", the injector body tries to react very rapidly. However, it can move only a very small distance relative to the operating sleeve because of the grease, and is thereby coupled to the operating sleeve through the said grease. The mass of the sleeve resists motion, and since the sleeve is being held firmly by the user, the mass of the user's hand is added to that of the sleeve, thus further reducing recoil motion.

In the accompanying drawings:

Figure 1 shows a section on the longitudinal axis of a first embodiment of a needleless injector according to the invention, with the components positioned to show the

device in mid-injection;

Figure 2 is an enlarged portion of the injector shown in Figure 1, showing the cooperating groove and key, and the trigger mechanism prior to operation;

Figure 3 is a section on the longitudinal axis of a second embodiment of needleless injector, and showing the injector prior to use; and

Figure 3a shows on a larger scale a latch used in Figure 3.

Referring to Figure 1, which shows the first embodiment of injector in mid-injection, the injector comprises an inner body 1 which is closely located within, but free to slide longitudinally with respect to, an operating sleeve 2. The sleeve 2 has a safety catch 20 integral therewith and pivotal with respect to the remainder of the sleeve by a living hinge 21. The latch is shown in the open position in Figures 1 and 2. The injector contains a medicament cartridge 3 which is firmly attached to the body 1, and which has a piston 4 slidingly and sealing located therein, in contact with medicament 5. As considered from the upper end of Figure 1, the piston comprises a cylindrical portion, a larger diameter cylindrical sealing portion, and a frusto-conical portion. The cartridge 3 has a discharge orifice 6.

Referring to Figure 2, which is an enlarged view of the injector trigger mechanism just prior to operation, injector body 1 houses a helical compression spring 10 which urges a ram 11 in direction of arrow W, but ram 11 is prevented from movement by a latch 8 engaging with a groove 12 on ram 11. The thrust of the ram 11 on latch 8 is taken on a face 13 of body 1, and the reaction of spring 10 is taken on a face 14 of body 1. Body 1 has a groove 15, and operating sleeve 2 has a key 16 which is a close sliding fit within the said groove. Groove 15 contains a viscous grease, which damps relative movement of the key 16 in groove 15: inso facto, relative movement between sleeve 2 and body 1 will be damped.

Referring to both Figures 1 and 2, which show the safety catch already in the open position of the injector is operated by grasping the operating sleeve 2 in the hand, and, placing orifice 6 onto the patient's skin 7, pressing in direction of arrow W. This causes the sleeve 2 to move relative to the body 1, causing a cam surface 9 to release latch 8 from groove 12 of ram 11. Spring 10 accelerates ram 11 rapidly in the direction of arrow W, so that it strikes piston 4 in cartridge 3 to dispense the injectate in known manner.

At the instant of release, the spring 10 urges ram 11 in the direction of arrow W, as described, but the spring also reacts on body 1 at face 14, so that the body 1 tries to move in the opposite direction to arrow W. There will be two reaction phases; the first at the instant of release, when the reaction force is on body 1 is against the mass of ram 11, and the second when the reaction force is against the combined mass of the cartridge 3 and body 1. However, this second reaction is within the closed combination of the firmly attached cartridge 3 and body 1, and there are few losses. However, the first reaction represents wasted energy, and furthermore tends to cause the body and cartridge combination to jump away from the injection site, thereby breaking the hydraulic connection to the skin and resulting in leakage of medicament. This first reaction is substantially reduced by the damping grease in groove 15.

Many variations in the described embodiment are possible. For example the damping grease may be retained within a circumferential groove on body 1 which is a close sliding fit within the operating sleeve 2 (see, for example, the embodiment of Figure 3). In all cases it is simple to vary the viscosity or running clearance to obtain the desired damping characteristics. Further modification to the damping characteristics are possible by using dilatant or shear-thickening compounds.

The use of a damping grease through which to apply the

trigger release conditions results in rate sensitivity - that is, if the operator applies a very high operating thrust to trigger the injector, at least some of this excessive force will be applied to the skin at the instant of injection. However, in practice, the range of forces applied by users is within sensible limits, and very consistent results are obtained.

The embodiment of Figure 3 is similar to that of Figures 1 and 2 in various respects, and elements in Figure 3 which correspond substantially to particular elements in Figures 1 and 2 are given the same reference numerals but increased by 100.

In the embodiment of Figure 3, the mechanical spring used in the embodiment of Figures 1 and 2 is replaced by a compressed gas spring. This is provided by a cylinder 130 which is closed at its upper end and which contains gas, typically air, under a pressure which is typically in the range 5.5 MPa (800 psi) to 20.7 MPa (3000 psi). The upper end of the ram 111 has a frustoconical portion 131 and a flange 132 between which is situated an O-ring seal 133. Prior to use, the ram 111 is held in the illustrated position by latch 108 engaging in a groove in the ram, the upper surface of the groove forming a cam surface 109. The latch 108 is shown on a larger scale in Figure 3a. At this point the latch is unable to move leftwards, because it bears against the inner wall of the sleeve 102.

The lower end of the cylinder 130 has an outwardly directed flange 130a, which enables the cylinder to be held by crimping the flange 130a beneath an outwardly directed flange 104a at the upper end of coupling 140. The sleeve 102 is formed of an upper portion 102a within which the cylinder is situated, and a lower sleeve portion 102b. The sleeve portion 102b is connected to the coupling by the interengaging screw threads 141 formed on the inner and outer walls of the sleeve portion 102b and coupling 140 respectively.

The orifice 106 is sealed by a resilient seal 134

which is held in place by a seal carrier 135. The seal carrier 135 is connected to the lower sleeve portion 102b by a frangible joint 136.

As a precaution against accidental firing, a tear-off band 137 is provided as the lower part of the upper sleeve portion 102a. The lower edge of the tear-off band 137 bears against a ring 142 which is bonded to the exterior surface of the coupling 140 or (not shown) formed integrally therewith. The function of the ring is to prevent downward movement of the sleeve portion 102a relative to the coupling 140, for so long as the tear-off band 137 is present. Accordingly, the ring 142 need not extend completely around the periphery of the coupling, and could be replaced by one or more separate elements.

An annular space 138 is formed in the inside wall of the sleeve 102. Where the sleeve is adjacent the cylinder 130, and the space is filled with a damping grease (indicated diagrammatically by a succession of black bands), so that the grease is in intimate contact both with the sleeve 102 and the cylinder 130. It should be noted that although a defined annular space is convenient from the point of view of providing a particular location for the grease, it could be omitted and the grease simply smeared over all or part of the outside of cylinder 130 and/or inside of sleeve 102.

When the embodiment of Figure 3 is to be operated, the user snaps off the seal carrier 135 at the frangible joint 136, which takes the seal 134 with it and exposes the orifice 106. The user then removes the tear-off band 137, and grasping the upper part of the sleeve 102 urges the orifice against the substrate (e.g. the user's own skin) which is to be injected. This moves the upper sleeve portion 102a downwardly, with respect to the lower sleeve portion 102b. This brings the aperture 130 into alignment with the latch 108, which is thus able to move sideways into the aperture under the influence of the force of gas within the cylinder 130 acting on the latch via the cam

surface 109 formed in the ram 111. The injector is thus caused to fire. As a precaution, in case the latch fails to move under the influence of the cam surface 109, an auxiliary cam surface 109a is provided on the inside of the sleeve portion 102a. As with the embodiment of Figures 1 and 2, the resulting recoil is damped by the damping grease.

By way of example only, the following are typical measurements for the embodiment of Figure 3:

Diametrical clearance between gas cylinder outside diameter and sliding sleeve inside diameter	0.05mm
Area of shear (i.e. cross section of grease) approximately	375mm ²
Viscosity of grease	2.2 Kilopoise
Momentum of ram at impact	0.06kg.m/s
Mass of sleeve portion 102a	1.3g
Mass of ram	2.5g
Impact gap between ram and piston	4mm
Gas pressure	6.2 MPa
Bore of gas cylinder	5.0mm

Whilst grease has been discussed as a preferred damping medium, similar results may be obtained by using air or oil damping devices - usually a cylinder and piston combination, i.e. a so-called "dashpot", wherein a fluid substance is caused to flow through a restriction, thereby to resist motion. Other viscous damping devices employ a vane, or a plurality of vanes, spinning in a damping medium, for example air, and these may be used if appropriate to the particular application.

CLAIMS:

1. A device for dispensing a material or article comprising a dispensing member movable, to effect dispensing, under the force of a spring which provides an energy store, and damping means, having a viscous damping medium, for damping recoil of the device during dispensing.
2. A device according to claim 1 in the form of a needleless injector having a liquid outlet.
3. A device according to claim 1, in the form of an actuator adapted, in conjunction with a cartridge, to form a needleless injector, the cartridge being filled with a liquid to be injected in a subject, and having a liquid outlet.
4. A device according to claim 3, adapted for use in conjunction with a cartridge having a free piston in contact with the liquid, the actuator comprising an impact member urged by the said spring and temporarily restrained by a latch, the impact member being movable in a first direction under the force of the spring to first strike the free piston and then to continue to move the piston in the first direction to expel a dose of liquid through the liquid outlet.
5. A device according to any one of claims 2 to 4, comprising a first, user-holdable member, and a second member which carries the liquid outlet, the first and second members being movable with respect to one another, said damping means being operable to damp movement of said first member with respect to said second member.
6. A device according to claim 5, wherein said damping means comprises a groove formed in one of said members and having the viscous medium therein, and an element which is

formed on the other said members and is arranged, in use, to travel through said viscous damping medium to effect damping.

7. A device according to any preceding claim, wherein the viscous damping medium is a grease.

8. A device according to any one of claims 1 to 5, wherein the viscous damping medium is an oil.

9. A device according to any one of claims 1 to 5, wherein the viscous damping medium is air.

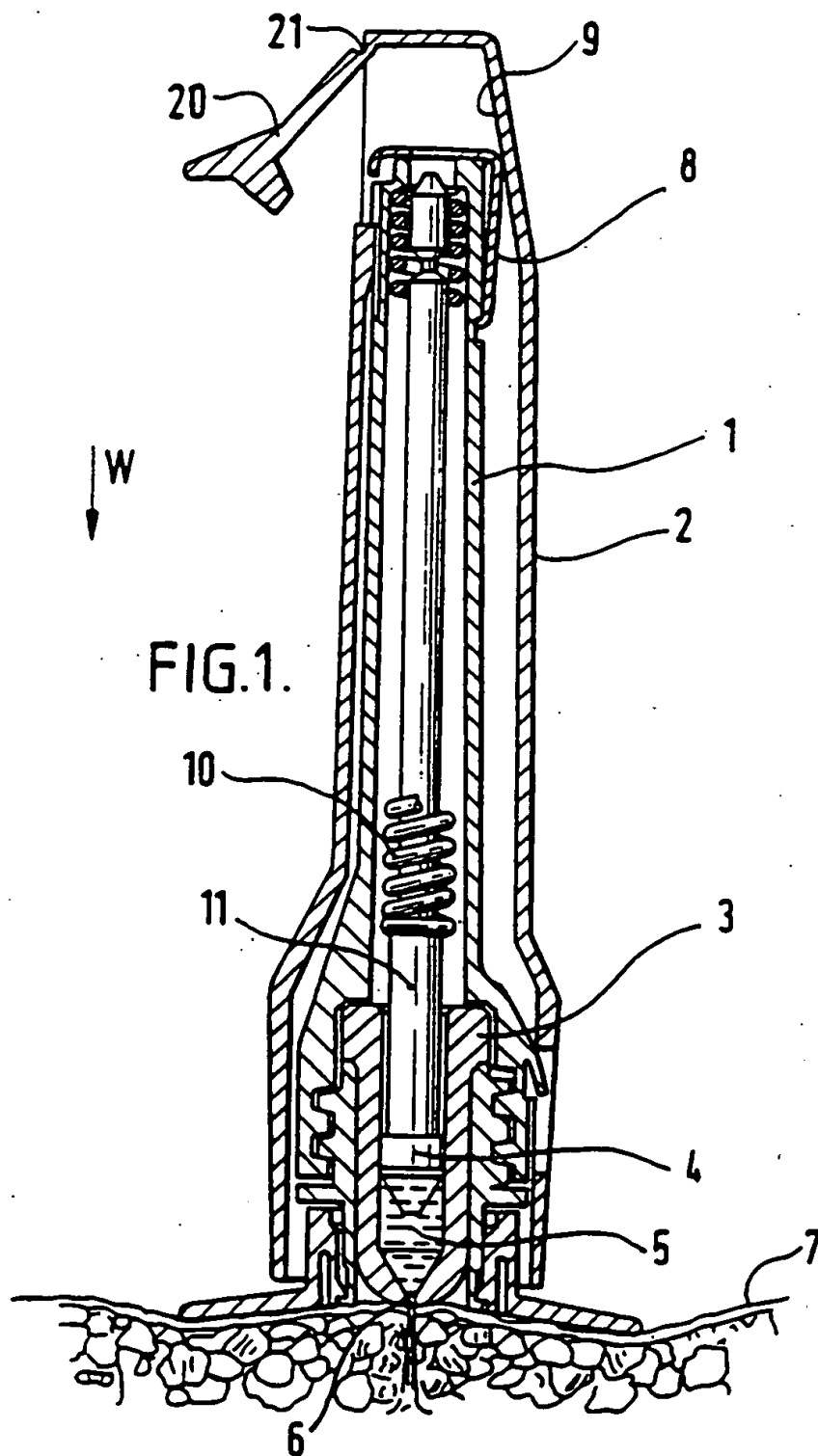
10. A device according to any one of claims 1 to 5, 8 or 9, wherein the damping means comprises a cylinder and piston arrangement forming a dashpot.

11. A device according to any one of claims 1 to 5, 8 or 9, wherein the damping means comprises a device having at least one vane spinning in the viscous damping medium.

12. A device according to any preceding claim, wherein said spring is a mechanical spring.

13. A device according to any one of claims 1 to 11, wherein said spring is a compressed gas spring.

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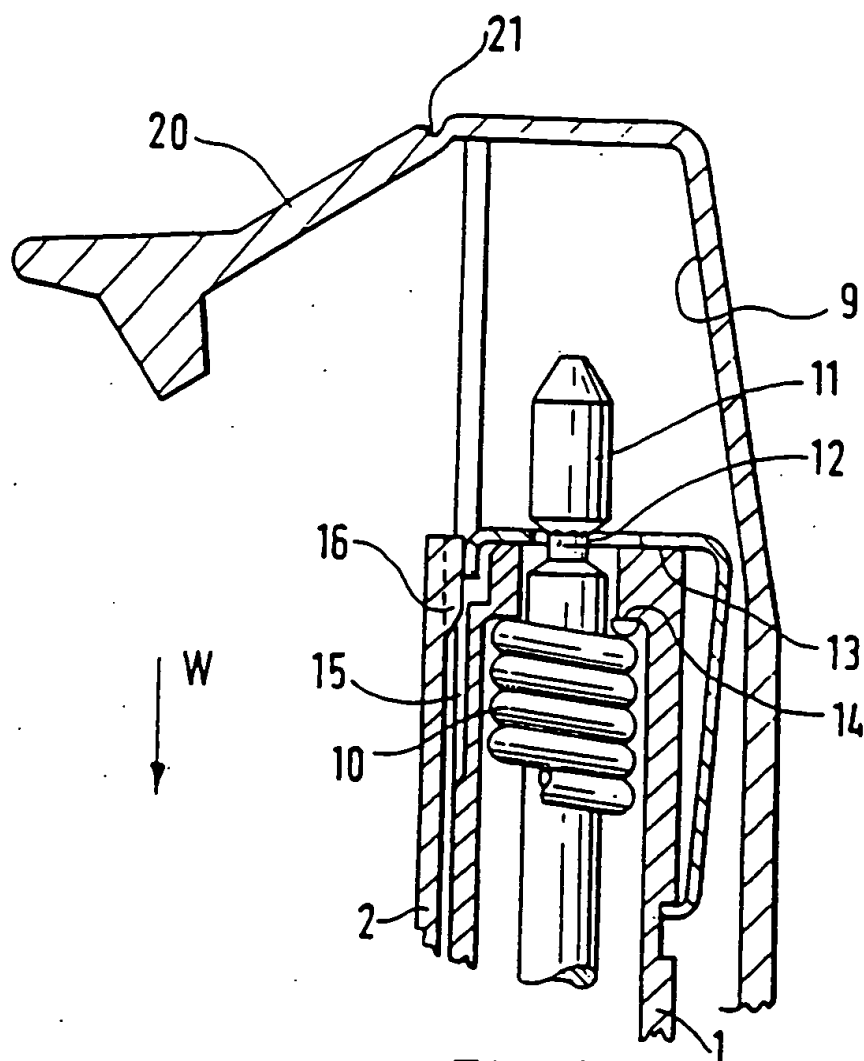
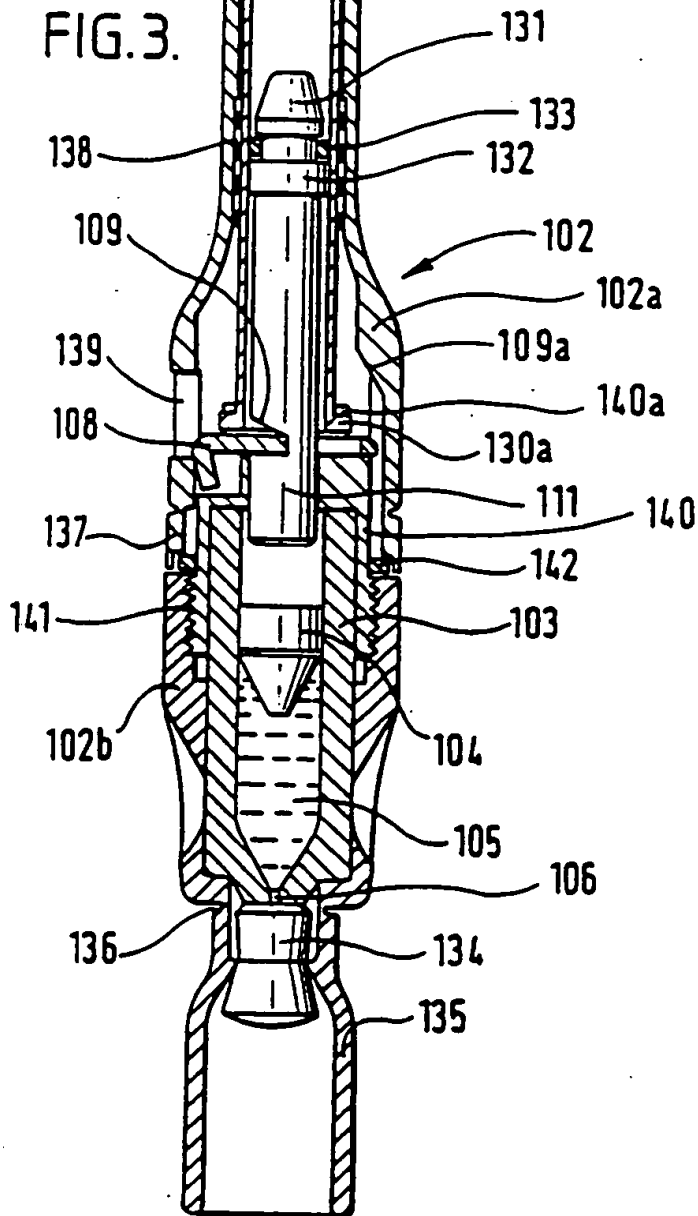
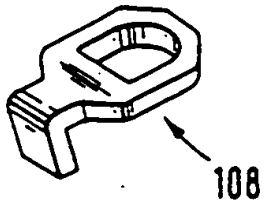


FIG. 2

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INTERNATIONAL SEARCH REPORT

Intern. Appl. No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M5/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	EP,A,0 510 826 (ETHICON INC) 28 October 1992 see column 10, line 52 - column 11, line 19; figures 20,22 ---	1,7
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A	EP,A,0 409 674 (PASTEUR MERIEUX SERUMS VACC) 23 January 1991 see column 7, line 51 - column 8, line 13; figure 3 ---	1-4,8,12
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☒ Further documents are listed in the continuation of box C.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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